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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,419	02/10/2004	Shubh D. Sharma	70025-US04-404	2914

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EXAMINER	
SACKEY, EBENEZER O	

ART UNIT	PAPER NUMBER
1624	

NOTIFICATION DATE	DELIVERY MODE
12/30/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/776,419	SHARMA ET AL.	
	Examiner	Art Unit	
	EBENEZER SACKEY	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *74 and 78-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *74 and 78* is/are allowed.

6)☒ Claim(s) *79-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/05/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 74 and 78-81 are pending.

This is in response to applicants RCE filed on 10/05/09.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/05/09 has been entered.

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed on 10/05/09 is acknowledged and has been entered into the file. A signed copy of the 1449 is attached herewith.

Claim Rejections - 35 USC § 102

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 74 and 78 under 35 U.S.C 102 (e) has been withdrawn.

Claim Rejections - 35 USC § 112

The rejection of claims 74 and 78 under 35 U.S.C. 112, second paragraph has been withdrawn.

The rejection of claim 78 under 35 U.S.C. 112, first paragraph has also been withdrawn.

Rejoinder

Method claims 79-81 will be rejoined with the compound and composition claims. However, a rejection of the said claims follows in view of the scope of the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 79-81 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating pathologic obesity and eating disorder, does not reasonably provide enablement for treating sexual dysfunction. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

1) Nature of invention.

2) State of prior art.

3) Level of ordinary skill in the art.

4) Level of predictability in the art.

5) Amount of direction and guidance provided by the inventor.

6) Existence of working examples.

7) Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention.

The claim is drawn to a method for treating sexual dysfunction with a *peptidomimetic* antagonist.

Applicants have not provided any definitive evidence to correlate the many disease categories of sexual dysfunction (few listed): sexual arousal disorder, sexual desire disorders, erectile dysfunction, and lack of orgasm, sexual pain and even the desire to want sex all the time. While treating specific sexual dysfunction has been linked to *peptidomimetic* antagonism (pages 1-3 of the specification), no specific sexual disorder in general has been associated with it.

2) State of the prior art.

Also note an online publication on priapism, which states that the condition (sexual dysfunction) is poorly understood. See: (www.leaddiscovery.co.uk/dossiers/MD1002/Sexual%20dysfunction.htm), and the

section titled “male sexual dysfunction”. The publication also states: Female sexual dysfunction represents a family of conditions that have few pharmacological therapies.

Thus, there is much evidence to question the efficacy of the scope of uses covered currently. Hence, the uses being urged are not currently available based on the activity relied on.

3) Level of ordinary skill in the art.

The intractability of the various disease states generally is clear evidence that the skill level in this art is low relative to the difficulty of the task.

4) Level of predictability in the art.

It is well established that “the scope of enablement varies inversely with the degree of unpredictability of the factors involved” and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher,* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)

Determining if any particular sexual dysfunction would be treatable with applicants’ compounds would require clinical trials in each disease state with each compound. Considering the hundreds of compounds covered by claim 74, and the different disease state, this is a very large degree of experimentation.

5) Amount of direction and guidance provided by the inventor

There are no directions concerning drug efficacy. Applicants have not disclosed formulations, doses or dosing schedules required to practice their invention or any correlation to any specific disease state.

6) Existence of working examples.

There is no working example of inhibiting any specific condition in the specification.

7) Breadth of claims.

The breadth of claim includes all of the compounds of formula (I) as well as the presently known and unknown list of sexual dysfunction embraced herein. Thus, the scope of the claim is broad.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation as disclosed in the specification because of the existence of the innumerable sexual dysfunction embraced by the claims. The skilled artisan would have numerous amounts of modifications to perform in order to arrive at the instantly claimed method.

Note the fact pattern in *Rasmusson vs. SmithKline Beechem* 75 U.S.P.Q. 2d. 1297, which was for treating prostate Cancer based solely on 5αR inhibition. The court found that evidence presented was **not** sufficient to show that "selective 5αR inhibitor in general or finasteride in particular, would be effective in treating prostate cancer". Evidence provided in that particular case pointed to more than one mechanism of action in treating cancer.

MPEP 2164.01(a) state, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the

application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright,* 999 F.2d 1557, 1562, 27, USPQ 2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to practice applicants' invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 79-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The above claims are of indeterminate scope because there are various categories of sexual dysfunction which read on the current claims. Categories of sexual dysfunction (few listed) are as follows: sexual arousal disorder, sexual desire disorders, erectile dysfunction, and lack of orgasm, sexual pain and even the desire to want sex all the time.

Claims 74 and 78 are allowed over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EBENEZER SACKEY whose telephone number is (571)272-0704. The examiner can normally be reached on 7.30-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ebenezer O. Sackey/
Patent Examiner, AU 1624.